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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/050,614 03/30/98 **BROWN** R F-5231 **EXAMINER** IM22/0804 DANIEL D RYAN FLEMING, M RYAN MAKI MANN AND HOHENFELDT ART UNIT PAPER NUMBER 633 WEST WISCONSIN AVENUE MILWAUKEE WI 53203 1723 DATE MAILED: 08/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/050,614

Michael A. Fleming

Applica: (s)

Examiner

Brown et al

Group Art Unit 1723



SEE OFFICE ACTION ON TH	
☐ Notice of Informal Patent Application, PTO-152	•
☐ Interview Summary, PTO-413☒ Notice of Draftsperson's Patent Drawing Review, PTO-948	3
	(s)5
X Notice of References Cited, PTO-892	
Attachment(s)	
Acknowledgement is made of a claim for domestic priority	vunder 35 U.S.C. § 119(e).
\square received in this national stage application from the $oldsymbol{I}$	nternational Bureau (PCT Rule 17.2(a)).
☐ received in Application No. (Series Code/Serial Num	
☐ received.	
☐ All ☐ Some* ☐ None of the CERTIFIED copies of	the priority documents have been
Acknowledgement is made of a claim for foreign priority u	nder 35 U.S.C. § 119(a)-(d).
Priority under 35 U.S.C. § 119	
☐ The oath or declaration is objected to by the Examiner.	
X The specification is objected to by the Examiner.	
☐ The proposed drawing correction, filed on	is approved disapproved.
X The drawing(s) filed on Mar 30, 1998 is/are objecte	ed to by the Examiner.
⊠ See the attached Notice of Draftsperson's Patent Drawing	Review, PTO-948.
Application Papers	
☐ Claims	are subject to restriction or election requirement.
Claim(s)	
Claim(s)	
Of the above, claim(s)	
	is/are pending in the application.
Disposition of Claims	
application to become abandoned. (35 U.S.C. § 133). Extension 37 CFR 1.136(a).	
A shortened statutory period for response to this action is set to is longer, from the mailing date of this communication. Failure to	expire 3 month(s), or thirty days, whichever
in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.	
☐ Since this application is in condition for allowance except for	formal matters, prosecution as to the merits is closed
This action is FINAL .	
X Responsive to communication(s) filed on May 26, 1998	

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DETAILED ACTION

Drawings

- The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because 1. reference character "160" has been used to designate both the axis of the umbilicus (page 16, line 27; Figures 1-2, 10) and the pin in the latch mechanism (page 6, line 21; Figure 2). Correction is required.
- The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do 2. not include the following reference sign(s) mentioned in the description: bottom wall 48 (page 6, line 35-page 7, line 1). Correction is required.
- The drawings are objected to because reference number "46" of Figure 4 should read 3. "64". Correction is required.
- 4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the facing high-G wall 44 (page 9, line 9) in Figure 6 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. M.E.P., § 608.02(d). Correction is required.
- 5. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the PRBC collection passage 98 (page 9, line 12) in Figure 6 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. M.E.P., § 608.02(d). Correction is required.

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Specification

6. The disclosure is objected to because of the following informalities: "channel 64" of page 8, line 10 should read "channel 42".

Appropriate correction is required.

7. The disclosure is objected to because of the following informalities: "interior seal 78" should read "interior seal 76".

Appropriate correction is required.

8. The disclosure is objected to because of the following informalities: "the lower block 124" of page 11, line 33-page 12, line 2 should read "the upper block 122" as shown in Figure 10.

Appropriate correction is required.

9. The disclosure is objected to because of the following informalities: "the upper block 122" of page 11, lines 2-5 should read "the lower block 124" as shown in Figure 10.

Appropriate correction is required.

10. The disclosure is objected to because of the following informalities: "channel 64" of page 14, line 20 should read "channel 42".

Appropriate correction is required.

11. The disclosure is objected to because of the following informalities: "channel 64" of page 15 (3 occurrences) should read "channel 42".

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes a number of ways in which the carrier may be constructed but there is not description of a thermally formed carrier (page 14, lines 23-25)

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not certain what the geometry of the channel is and if a different geometry from the processing container is necessary for the invention.

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Claim Rejections - 35 USC § 102

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16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 17. Claims 1-3, 5-6, 11-14, 16-17, 19-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Alterbaum (US 4,714,457).

Alterbaum discloses a processing assembly comprising a processing container 1 and a carrier 6 as recited in instant claim 1.

Alterbaum discloses a processing assembly comprising a centrifugal channel 8, processing container 1, and a carrier 6 as recited in instant claim 2.

Alterbaum discloses a centrifuge channel including a curved region (Figure 5). (Instant Claim 3)

The carrier is pre-shaped. (Instant Claim 5)

The carrier is molded to retain the processing container in a flexed condition (Figure 5).

(Instant Claim 6)

The carrier comprises plastic material (column 5, lines 44-45). (Instant Claim 11)

The processing container is secured to the carrier (Figure 5). (Instant Claim 12)

The carrier includes first and second facing surfaces and an intermediate slot (Figure 5).

(Instant Claim 13)

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The carrier includes a surface contour which defines a wall contour (Figure 5). (Instant Claim 14)

The processing container has a normal geometry (Figure 5). (Instant Claim 16)

The assembly includes an umbilicus 2. (Instant Claim 17)

Alterbaum discloses a blood processing assembly comprising a centrifugal channel 8, processing container 1, tubing 2 including a umbilicus (Instant Claim 20), and a carrier 6 as recited in instant claim 19.

The centrifuge channel includes a curved region (Figure 5). (Instant Claim 21)

Alterbaum discloses a method of manufacturing comprising the step of attaching a carrier to a blood processing container (Figure 5). (Instant Claim 22)

Alterbaum discloses a method of processing blood comprising the steps of attaching a carrier to a blood processing container, inserting the processing container into the centrifugation chamber, and performing a blood processing procedure (Figure 5). (Instant Claim 23)

18. Claims 1-6, 11-17, 19-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schroendorfer (US 4,445,883).

Schroendorfer discloses a processing assembly comprising a processing container 8 and a carrier 10 as recited in instant claim 1.

Schroendorfer discloses a processing assembly comprising a centrifugal channel (Figure 4), processing container 8, and a carrier 10 as recited in instant claim 2.

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Schroendorfer discloses a centrifuge channel including a curved region (Figure 4).

(Instant Claim 3)

The carrier is adapted to assume a generally lay-flat configuration in the absence of external force (Figure 3). (Instant Claim 4)

The carrier is pre-shaped. (Instant Claim 5)

The carrier is molded to retain the processing container in a flexed condition (Figure 5).

(Instant Claim 6)

The carrier comprises plastic material (column 5, lines 60-64). (Instant Claim 11)

The processing container is secured to the carrier (Figure 4). (Instant Claim 12)

The carrier includes first and second facing surfaces and an intermediate slot (column 5, lines 64-67). (Instant Claim 13)

The carrier includes a surface contour which defines a wall contour (Figure 4). (Instant Claim 14)

The carrier includes a surface projection which defines a wall projection the processing container (Figure 3). (Instant Claim 15)

The processing container has a normal geometry (Figure 4). (Instant Claim 16)

The assembly includes an umbilicus 20. (Instant Claim 17)

Schroendorfer discloses a blood processing assembly comprising a centrifugal channel (Figure 4), processing container 8, tubing 20 including a umbilicus (Instant Claim 20), and a carrier 10 as recited in instant claim 19.

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The centrifuge channel includes a curved region (Figure 4). (Instant Claim 21)

Schroendorfer discloses a method of manufacturing comprising the step of attaching a carrier to a blood processing container (Figure 4). (Instant Claim 22)

Schroendorfer discloses a method of processing blood comprising the steps of attaching a carrier to a blood processing container, inserting the processing container into the centrifugation chamber, and performing a blood processing procedure (Figure 4). (Instant Claim 23)

19. Claims 1-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mitchell et al (US 3,674,197).

Mitchell discloses a processing assembly comprising a processing container 48 and a carrier 11, 12 as recited in instant claim 1.

Mitchell discloses a processing assembly comprising a centrifugal channel (Figure 3), processing container 48, and a carrier 11, 12 as recited in instant claim 2.

Mitchell discloses a centrifuge channel including a curved region (Figure 3). (Instant Claim 3)

The carrier is adapted to assume a generally lay-flat configuration in the absence of external force (Figure 5). (Instant Claim 4)

The carrier is pre-shaped. (Instant Claim 5)

The carrier is molded to retain the processing container in a flexed condition (Figure 5).

(Instant Claim 6)

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The carrier may be injection molded or otherwise formed (column 2, lines 31-40).

(Instant Claims 7-8)

The carrier may comprise of any suitable material (column 2, lines 31-40). (Instant Claims 9-10, 18)

The carrier comprises plastic material (column 2, lines 31-40). (Instant Claim 11)

The processing container is secured to the carrier (Figure 1). (Instant Claim 12)

The carrier includes first and second facing surfaces and an intermediate slot (Figure 2).

(Instant Claim 13)

The carrier includes a surface contour which defines a wall contour (Figure 2). (Instant Claim 14)

The carrier includes a surface projection which defines a wall projection for the processing container (Figure 2). (Instant Claim 15)

The processing container has a normal geometry (Figure 2). (Instant Claim 16)

The assembly includes an umbilicus 54, 56. (Instant Claim 17)

Mitchell discloses a blood processing assembly comprising a centrifugal channel (Figure 3), processing container 48, tubing 54, 56 including a umbilicus (Instant Claim 20), and a carrier 11, 12 as recited in instant claim 19.

The centrifuge channel includes a curved region (Figure 3). (Instant Claim 21)

Mitchell discloses a method of manufacturing comprising the step of attaching a carrier to a blood processing container (Figure 2). (Instant Claim 22)

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Mitchell discloses a method of processing blood comprising the steps of attaching a carrier to a blood processing container, inserting the processing container into the centrifugation chamber, and performing a blood processing procedure (Figures 2-3). (Instant Claim 23)

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Moore et al discloses a centrifuge insert having wall projections.

Harmony et al discloses a carrier having a geometry unlike the processing container.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Fleming whose telephone number is (703) 305-0748. The examiner can normally be reached on Monday-Thursday from approximately 9:30 AM - 3:00 PM and on Friday from approximately 9:30 AM - 1:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. L. Walker, can be reached on (703) 308-0457.

The fax phone number for **Unofficial** faxes (i.e. faxes not to be entered, drafts) for Technology Center 1700 is **(703)** 305-3602. The fax number for **Official** faxes (i.e. faxes to become part of the file history) for this Center is **(703)** 305-3599. When filing a fax in Technology Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communication with the

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PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

M. A. Fleming

July 6, 1999

W. L. WALKER
PRIMARY EXAMINER
GROUP 1300